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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,580	10/09/2001	Douglas L. Michalsky	CMI-470	6015

7590 02/17/2004

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EXAMINER
FRANK, RODNEY T

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,580	MICHALSKY ET AL.	
	Examiner	Art Unit	
	Rodney T. Frank	2856	

-- The MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *37-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36 and 43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-36 and 43-50 in Paper dated October 20, 2003 is acknowledged. The traversal is on the ground(s) that claims 37-42 would present no additional search burden. This is not found persuasive because there is an additional burden of search. First of all, the elected claims are directed toward a prosthetic heart valve testing apparatus and method, while claims 37-42 are directed toward heart valves that may or may not be prosthetic, according to the language of the claims. Second, there are distinct structural differences between the apparatus claims of the elected group and the apparatus claim of independent claim 37 that would not require a search for one group and the other (for example, there is no slide plate in claims 37 - 42 and there is no computer or controller mentioned in claims 1-35 or 43-50). For at least these reasons, the restriction requirement is deemed proper. With concern fro the species election, the examiner does agree that there is no need to restrict based upon a species as there only appears to be one species described in claims 1-36 and 43-50, and therefore, all claims in the elected group will be examined on the merits.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-36 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickard (U. S. Patent Number 4,682,491). Pickard discloses an apparatus and method for testing prosthetic heart valves prior to implant in the human body provides a test chamber having a flow channel therethrough and a passageway which receives a mounting fixture for a heart valve. The test chamber is used in a mock circulatory loop with the flow channel being in the loop. Preferably, the test chamber has a transverse passageway that intersects the flow channel, and the mounting fixture advances completely through the test chamber from an insertion location to a disconnect location while a dynamic seal is maintained. Two such test chambers may be used in a mock loop, and the loop is configured with an intake chamber fluidly interconnecting one side of each test chamber, and a restriction chamber fluidly interconnecting the other sides of the test chambers. The restriction chamber is variable, and pressure compensation is provided between each of test chambers and the restriction chamber. A pump cyclically drives a fluid through the loop, and flow meters and pressure sensors monitor the test. A data processor monitors and processes the flow data and controls the pump to create a desired flow waveform. The test can also be visually and optically monitored (Please see the Abstract).

In reference to independent claims 1, 14, and 26, Pickard discloses a prosthetic heart valve testing apparatus with a test chamber (126, figure 4) this test chamber includes a cylinder shown in figure 5 that is used to hold the valve under test and this cylinder, as shown in figure 4, sits in a fluid until it is placed in position in the testing chamber slot from a reservoir into the testing stream via mouth 212. These cylinders are capable to be pre-loaded and stacked together for sequential manual or mechanical/automated loading as disclosed in column 10 line 50 through column 11 line 5. The loading cylinders are able to be slid into place, much as the sliding plate claimed in the present invention. It is the opinion of the examiner that the loading cylinders of the Pickard

reference would serve the same purpose as the slide plate, storage member, and load/unload means of the independent claims, and no advantage would be derived from separating these means into separate components. Therefore, the device disclosed in the independent claims 1, 14, and 26 is disclosed in view of the teaching of Pickard.

In reference to claims 2, 15, and 27, the differential pressure sensors are shown in, for example, figure 4 as item 146.

In reference to claims 3, 16, and 28, a pump for circulating the test fluid through the circulatory loop of the Pickard reference is disclosed.

In reference to claims 4, 17, and 29, there is disclosed a restriction/compliance chamber (130) and a variable/pinch valve (306) as shown in figure 3 of the Pickard reference.

In reference to claims 5, 6, 18, 19, and 30-31, though the specific materials of the test chamber and cylinder are not disclosed, these materials are a mere design choice that would be obvious to one of ordinary skill in the art.

In reference to claims 7, 9, 20, 22, and 32 it is disclosed that the cylinder is sealed to the testing bore via O-rings (see figure 4, item 220 or figures 4 or 5 item 218).

In reference to claims 8, 11, 21, 23, 33, and 35 though the use of a stepping motor is not specifically disclosed, since it is disclosed that a mechanical means of loading and rotation can be used, then the use of a stepping motor or any other mechanical system to load and/or rotate the testing cylinders in place of the testing flow would have been obvious to one of ordinary skill in the art.

In reference to claims 10, 12, 13, 24, 25, 34, and 36, it is disclosed and shown in figure 5 that the cylinder, which acts as a storage member, has a plurality of openings (268), which are

adapted to have the prosthetic heart valve placed therein. It is also disclosed by Pickard that the cylinder can be rotated within the test chamber.

In reference to the method claims 43-50, since the device is disclosed, then the method of using the components of the device would also be obvious to one of ordinary skill in the art. Further, the operation method of the device is disclosed in column 15 line1 and concludes in column 16 line 17.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney T. Frank whose telephone number is (571) 272-2193. The examiner can normally be reached on M-F 9am -5:30p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0956.

RTF
January 22, 2004

HEZRON WILLIAMS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800